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Docket No. CRD-5065

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Robert Falotico et al.

Serial No. : 10/780,596

Art Unit: 3761

Filed : February 18, 2004

Examiner: Hieu Phan

For : LOCAL VASCULAR DELIVERY OF CLADRIBINE IN  
COMBINATION WITH RAPAMYCIN TO PREVENT RESTENOSIS  
FOLLOWING VASCULAR INJURY

I hereby certify that this correspondence is being deposited with the  
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November 1, 2005

(Date of Deposit)

Carl J. Evens

(Name of applicant, assignee, or Registered Representative)

/Carl J. Evens/

(Signature)

November 1, 2005

(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e)  
(attached); or

☐ Please charge Deposit Account No. 10-  
0750/ / the fee of \$180.00 as set forth  
in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a) (2).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/CRD5065/CJE. This form is submitted in triplicate.

Respectfully submitted,

/Carl J. Evens/

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DATED: November 1, 2005



PTO/SB/08A (08-00)  
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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 4

Application Number	10/780,596
Filing Date	February 18, 2004
First Named Inventor	Robert Falotico
Group Art Unit	3761
Examiner Name	
Attorney Docket Number	CRD5065USANP

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		3,929,992		Sehgal et al.	12/30/1975	
		3,959,078		Guire et al.	05/25/1976	
		4,350,160		Kolesov et al.	09/21/1982	
		4,366,819		Kaster	01/4/1983	
		4,624,257		Berggren et al.	11/25/1986	
		4,722,906		Guire et al.	02/02/1988	
		4,733,665		Palmaz	03/29/1988	
		4,739,762		Palmaz	04/26/1988	
		4,776,337		Palmaz	10/11/1988	
		4,917,090		Berggren et al.	04/17/1990	
		4,917,091		Berggren et al.	04/17/1990	
		5,229,172		Cahalan et al.	07/20/1993	
		5,234,447		Kaster et al.	08/10/1993	
		5,308,641		Cahalan et al.	05/03/1994	
		5,350,800		Cahalan et al.	09/27/1994	
		5,415,938		Cahalan et al.	05/16/1995	
		5,837,313		Ding et al.	11/17/1998	
		6,099,562		Ding et al.	08/08/2000	
		6,120,536		Ding et al.	09/19/2000	
		6,153,252		Hossainy et al.	11/28/2000	
		6,425,898	B1	Wilson et al.	07/30/2002	

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 4

<i>Application Number</i>	10/780,596
<i>Filing Date</i>	February 18, 2004
<i>First Named Inventor</i>	Robert Falotico
<i>Group Art Unit</i>	3761
<i>Examiner Name</i>	
<i>Attorney Docket Number</i>	CRD5065USANP

## FOREIGN PATENT DOCUMENTS

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE  STATEMENT BY APPLICANT</b> (use as many sheets as necessary) Sheet 3 of 4	<b>Application Number</b>	10/780,596
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	<b>Group Art Unit</b>	3761
	<b>Examiner Name</b>	
	<b>Attorney Docket Number</b>	CRD5065USANP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		CLOWES, A.W and KARNOVSKY M., Nature 265:25-26, 1977	
		GUYTON, J.R. ET AL., Circ. Res., 46:625-634, 1980	
		CLOWES, A.W. AND CLOWES, M.M., Lab. Invest. 52:611-616, 1985	
		CLOWES, A.W. AND CLOWES, M.M., Circ. Res. 58:839-845, 1986	
		MAJESKY ET AL., Circ. Res. 61:296-300, 1987	
		SNOW ET AL., Am. J. Pathol. 137:313-330, 1990	
		OKADA T. ET AL., Neurosurgery 25: 92-98, 1989	
		CURRIER, J.W. ET AL., Circ. 80:11-66, 1989	
		SOLLOT, S.J. ET AL., J. Clin. Invest. 95: 1869-1876, 1995	
		POWELL, J. S. ET AL., Science, 245: 186-188, 1989	
		LUNDERGAN, C. F. ET AL., Am J. Cardio. 17 (Suppl. B): 132B-136B, 1991	
		JONASSON, I. ET AL., Proc. Natl., Acad. Sci., 85: 2303, 1988	
		FERNES, G.A.A., ET AL., Science 253: 1129-1132, 1991	
		NEMECEK, G.M. ET AL., J. Pharmacol Exp. Thera. 248: 1167-1174, 1989	
		LIU, M.W. ET AL., Circ. 81: 1089-1093, 1990	
		FUKUYAMA, J. ET AL., Eur. J. Pharmacol. 318: 327-332, 1996	
		HANSSON, G.K. AND HOLM, J. Circ. 84: 1266-1272, 1991	
		MARX, S.O. ET AL., Circ. Res. 76: 412-417, 1995	
		COLBURN, M.D. ET AL., J. VASC. SURG. 15: 510-518, 1992	
		BERK, B.C. ET AL., J. Am. Coll. Cardiol. 17: 111B-117B, 1991	
		WEINBERGER, J. ET AL., Int. J. Rad. Onc. Biol. Phys. 36: 767-775, 1996	
		FARB, A. ET AL., Circ. Res. 80:542-550, 1997	
		SIMONS, M. ET AL., Nature 359: 67-70, 1992	
		CHANG, M.W. ET AL., J. Clin. Invest. 96: 2260-2268, 1995	
		MODERN FLUOROPOLYMERS, (J Shires ed.), John Wiley & Sons, New York, 1997, pp. 77-87	
		AJROLDI, ET AL., Fluoroelastomers-dependence of relaxation Phenomena on Compositions, Polymer 30, 2180, 1989	
		HANSON & HARKER, Proc. Natl. Acad. Sci. USA 85:3184-3188, 1988	

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Sheet 4 of 4

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<b>Group Art Unit</b>	3761
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	CRD5065USANP

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